

## **REMARKS**

Applicants have the following comments and evidence in support of this amendment and in response to the Final Rejection of May 4, 2007.

### **Entry of Amendment and Declaration**

As Applicants are filing a RCE herewith, this amendment and the accompanying Declaration of Dr. Peter Hersey should be entered and considered at this time.

### **Declaration of Peter Hersey**

In support of the present application and in response to the Final Rejection, Applicants are submitting herewith the Declaration of Dr. Peter Hersey. As shown in the Declaration, Dr. Hersey is a medical doctor and expert in medical oncology, including therapeutic cancer research and clinical practice. Dr. Hersey is also an expert in the development and use of chemotherapeutic, radiosensitizer, and immunotherapy medicaments for treatment of melanoma and other cancers.

As explained in more depth below, Dr. Hersey's Declaration is evidence of the non-obviousness of the claimed invention and clearly rebuts the Examiner's obviousness rejection.

Accordingly, it is respectfully requested that this declaration be entered and considered at this time.

### **Claim Amendments**

The claimed pharmaceutical compositions of the present application are directed to formulations of certain new and novel highly-halogenated halogenated xanthenes containing a

multiplicity of both iodine and bromine atoms, including 4,5,6,7-Tetrabromoerythrosin, that the inventors have created and designed into a chemotherapeutic pharmaceutical composition.

While Applicants traverse the rejections in the Final Rejection, in order to advance prosecution of the present application, Applicants are amending independent Claims 1, 36 and 37, and canceling Claims 19 and 27, as outlined below.

Independent Claim 1 has been amended to limit the scope of the claimed injectable composition to those formulated using certain highly-halogenated halogenated xanthenes containing a multiplicity of both iodine and bromine atoms, specifically 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, and Tribromoerythrosin. The compositions of matter represented by these key active ingredients are novel in light of all known prior art. Independent Claims 36 and 37 have been similarly amended.

While Applicants traverse the Examiner's basis for rejection of independent Claim 19 over Heitz (specifically the cited passage at col. 5, lines 25-28 in Heitz), Applicants are canceling Claim 19 (and Claim 27 dependent thereupon) without prejudice or disclaimer in order to advance prosecution of the present application.

As explained below, the pending claims are in an allowable condition, and it is respectfully requested that they be allowed.

#### Novel Composition of Matter

Amended independent Claims 1, 36 and 37 are directed to various injectable pharmaceutical compositions that contain new and novel, highly-halogenated halogenated xanthenes (i.e., 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, and Tribromoerythrosin), none

of which are believed to have been described or suggested in the prior art, especially that art cited by the Examiner in this or any of the prior actions for this application. As explained below, the compounds are not obvious extensions of those compounds previously known. Applicants are submitting the Declaration of Dr. Peter Hersey in support of the novel and non-obviousness of these compounds.

More specifically, the Colour Index<sup>1</sup> lists a large number of fluorescein analogs that are referenced by Heitz.<sup>2</sup> These analogs contain various heteroatoms (such as halogens) or functionalities (such as hydroxyl, carboxyl, alkyl, aryl, nitro or thiol groups) at the 4, 5, 6, 7, 2', 4', 5' and 7' positions. Some of these analogs, such as Phloxine B and Rose Bengal, contain halogens at each of these positions. However, whereas Applicants' claimed halogenated xanthenes require substitution of fluorescein at the 2', 4', 5' and 7' positions with 4 atoms of iodine and at the 4, 5, 6 and 7 positions with 1 to 4 atoms of bromine, *no such compounds* are represented in the Colour Index. Furthermore, despite the lengthy, comprehensive listing of compounds in the Colour Index, only five of the compounds listed have 5 or more halogens at any of these positions, and none of these contain both iodine and bromine, as in the claimed compounds. Thus, the Colour Index does not disclose any of the Applicants' claimed compounds or any closely related compounds. A complete listing of the fluorescein analogs in the Colour Index, along with Applicants' claimed compounds, are provided in Table A herein.

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<sup>1</sup> This document was previously made of record in this application. Heitz, which is relied upon by the Examiner to reject the present application, references the Colour Index in those portions relied upon by the Examiner.

<sup>2</sup> All fluorescein analogs listed by Heitz are described in detail in the Colour Index.

Table A. Fluorescein Derivatives Listed in the Colour Index and Applicants' Claimed Compounds

CI No.	Name	2'	4'	5'	7'	4	5	6	7	Ester	Hydroxyl (6')
45350	Fluorescein	H	H	H	H	H	H	H	H	H	H
45355	Thiofluorescein	H	H	H	H	H	SH	SH	H	Na	H
45360	Acid Yellow 74	CH <sub>2</sub> Ar	H	H	H	H	H	H	H	Na	Na
45365	Solvent Orange 32	H	Cl	Cl	H	H	H	H	H	Na	Na
45366	Solvent Red 42	Cl	Cl	Cl	Cl	H	H	H	H	H	H
45370	Acid Orange 11	H	Br	Br	H	H	H	H	H	Na	Na
45371	Solvent Orange 18	I	Br	Br	I	H	H	H	H	H	H
45375	Phloxine N	H	Br	Br	H	Cl	H	H	Cl	Na	Na
45376	Thiophloxine	Br	SH	SH	Br	Cl	H	H	Cl	K	K
45380	Acid Red 87 (Eosin Y)	Br	Br	Br	Br	H	H	H	H	Na	Na
45385	Solvent Red 44	Br	Br	Br	Br	H	H	H	H	CH <sub>3</sub>	K
45386	Solvent Red 45	Br	Br	Br	Br	H	H	H	H	C <sub>2</sub> H <sub>5</sub>	K
45390	Mordant Dye (Chromoxane Brilliant Red RD)	Br	Br	Br	Br	H	CO <sub>2</sub> H	OH	H	H	H
45395	Solvent Dye	NO <sub>2</sub>	H	H	NO <sub>2</sub>	H	H	H	H	H	H
45396	Solvent Orange 16	H	NO <sub>2</sub>	NO <sub>2</sub>	H	H	H	H	H	H	H
45400	Acid Red 91	NO <sub>2</sub>	Br	Br	NO <sub>2</sub>	H	H	H	H	Na(NH <sub>4</sub> )	Na
45405	Acid Red 98 (Phloxine)	Br	Br	Br	Br	Cl	H	H	Cl	K	K
45410	Acid Red 92 (Phloxine B)	Br	Br	Br	Br	Cl	Cl	Cl	Cl	Na	Na
45415	Cyanosine	Br	Br	Br	Br	Cl	Cl	Cl	Cl	CH <sub>3</sub>	K
45420	Cyanosine B	Br	Br	Br	Br	Cl	Cl	Cl	Cl	C <sub>2</sub> H <sub>5</sub>	Na
45425	Acid Red 95 (Erythrosine 6G)	H	I	I	H	H	H	H	H	Na	Na
45430	Acid Red 51 (Erythrosine)	I	I	I	I	H	H	H	H	Na	Na
45435	Acid Red 93	I	I	I	I	Cl	H	H	Cl	Na	Na
45440	Acid Red 94 (Rose Bengal)	I	I	I	I	Cl	Cl	Cl	Cl	Na	Na
45445	Mordant Violet 25	H	OH	OH	H	H	Cl	Cl	H	Na	Na
45450	Chromoxane Red B	CO <sub>2</sub> H	CH <sub>3</sub>	CH <sub>3</sub>	CO <sub>2</sub> H	H	H	H	H	Cl (replaces CO <sub>2</sub> H)	H
45455	Chromoxane Red Violet 1358	CO <sub>2</sub> H	CH <sub>3</sub>	CH <sub>3</sub>	CO <sub>2</sub> H	H	H	H	H	Cl (replaces CO <sub>2</sub> H)	H
45456	Solvent Orange 17	CO <sub>2</sub> H	Br	Br	CO <sub>2</sub> H	H	H	H	Br	H	H
45457	Solvent Red 46	CO <sub>2</sub> H	Br	Br	CO <sub>2</sub> H	H	H	H	Br	H	H
Applicants' Claimed Compounds											
NA	4, 5, 6, 7-Tetrabromoerythrosin	I	I	I	I	Br	Br	Br	Br	Na	Na
NA	Monobromoerythrosin	I	I	I	I	H	H	H	Br	Na	Na
NA	Dibromoerythrosin	I	I	I	I	Br	H	H	Br	Na	Na
NA	Tribromoerythrosin	I	I	I	I	Br	Br	H	Br	Na	Na

As is clear from the listing in Table A, the alleged prior art (as exemplified by the Colour Index) does not describe nor is it remotely similar to Applicants' claimed compounds. For example, none of these listed compounds contain four iodine atoms at positions 2', 4', 5' and 7' *along with* one or more bromine atoms at any of positions 4, 5, 6 or 7, as in the claimed compounds. Thus, the prior art does not disclose or suggest Applicants' novel compounds of 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, or Tribromoerythrosin, which are the basis for the claimed pharmaceutical compositions. See also Hersey Declaration ¶¶7.

The novelty of the compounds claimed by Applicants is the result, at least in part, of the relative complexity of synthesis of these new compounds that is posed by steric hindrance<sup>3</sup> from the dense content of halogens, along with other factors such as photochemical instability that make such compounds relatively difficult to produce, handle, store and use. Applicants submit that they are the first to invent the claimed new compounds which represent a novel extension to the halogenated xanthene family. For example, Rose Bengal (a very stable molecule which formerly comprised the most halogen-rich member of the halogenated xanthene family, as evidenced by the listing in Table A) has been known for over 100 years. Nonetheless, knowledge of its properties and those of the other previously known halogenated xanthenes (such as Phloxine B, Erythrosin, and Eosin) has not led those skilled in the art (prior to Applicants' conception) to conceive, suggest, synthesize or investigate Applicants' claimed highly-halogenated halogenated xanthenes. See e.g. Hersey

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<sup>3</sup> Steric hindrance is spatial interference inhibiting or preventing the close arrangement of adjacent atoms within a molecule due to the sizes of the overlapping electron clouds of the adjacent atoms, and poses particularly difficult synthetic challenges when large atoms, such as bromine and iodine, are incorporated into a molecule.

Declaration ¶11. Nor has anyone else conceived of pharmaceutical compositions consisting of halogenated xanthenes for any chemotherapeutic treatment prior to Applicants' work. Id.

As Dr. Hersey explains, the claimed compounds are the result of a highly specific pattern of chemical substitution. Hersey Declaration ¶8. It is highly unlikely one skilled in the art would have arrived at such compounds, unless one already knew the compound. The claimed compounds are the result of highly specialized starting materials that require combination in a very specific way to result in the claimed compounds. Once the compound has been conceived, then the starting compounds and process are clear. For example, 4,5,6,7-Tetrabromoerythrosin requires condensation of resorcinol with tetrabromophthalic anhydride, followed by iodination of the resulting intermediate with I<sub>2</sub>. Since tetrabromophthalic anhydride is not a standard compound, this crucial starting material itself would require custom synthesis. Hersey Declaration ¶8. It would be nearly impossible, however, to start with the broad, general disclosure in Heitz and then arrive at the claimed compounds.

Applicants conceived of these new compounds in an effort to improve chemotherapeutic treatment of diseases of human tissue, the performance of which may be enhanced by increasing the halogen density of the halogenated xanthene molecules, for example by including greater numbers of halogen atoms or increasing their atomic number. A consequence of such enrichment is greatly reduced stability of the xanthene molecule, especially upon exposure to optical radiation. Such trends in synthetic complexity and instability run counter to the teachings of the prior art (such as that of Heitz, as cited by the Examiner in the present Office Action) which are predicated on use of relatively stable, inexpensive molecules that are added to livestock feed. Since such animals are unlikely to be fed in the dark, investigators such as Heitz presumably would not consider developing

or using photochemically unstable analogs of the halogenated xanthenes, nor would they likely select new analogs requiring complex (and presumably relatively expensive) synthesis. In the case of the Colour Index, this reference is primarily concerned with molecules of value for use as dyes. Since dyes generally must be stable in the presence of light (a dye is of dubious value if it must be kept and used in the dark since it requires light to be seen), as with Heitz, this reference would not be expected to be concerned with the relatively unstable molecules discovered by Applicants. Hence, prior investigators had no reason and were not motivated to consider or investigate, and there is no evidence that they conceived of or considered, Applicants' novel compounds since these compounds would have no obvious relevance for the uses employed by such investigators.

Accordingly, the claimed highly-halogenated halogenated xanthenes, and the various claimed pharmaceutical compositions containing such highly-halogenated halogenated xanthenes, of the claims of the present application are novel over the prior art.

#### Final Rejection

Applicants appreciate the Examiner's withdrawal of many of the prior objections and rejections.

Applicants will now address the Examiner's remaining rejection in the Final Rejection.

#### Claim Rejections – 35 USC §103

In the Final Rejection, the Examiner rejects Claims 1-2, 9-11, 19, 27, 36 and 37 under 35 USC §103(a) as being unpatentable over Heitz. This rejection is respectfully traversed.

While Applicants traverse this rejection, in order to advance the prosecution of this application, Claims 19 and 27 have been canceled without prejudice or disclaimer, rendering the rejection of these claims moot.

As explained in depth below, the rejection of the remaining claims (i.e. Claims 1-2, 9-11, 36 and 37) is traversed. Applicants respectfully submit that Heitz does not disclose or suggest the novel, non-obvious, highly-halogenated halogenated xanthenes recited in independent Claims 1, 36 and 37, and in particular, as evidenced by the listing of compounds cited in Table A herein, neither Heitz nor the reference cited in Heitz (i.e., the Colour Index) discloses or suggests the claimed compounds, nor the pharmaceutical compositions of which they are a part.

Applicants believe that it cannot be disputed that Heitz does not specifically disclose the claimed compounds. The Examiner, however, contends that the known halogenated xanthene dyes in Heitz can be manipulated to arrive at Applicants' claimed halogenated xanthenes and that the vague disclosure in Heitz encompasses the claimed compounds.

It is respectfully submitted that such a rejection is improper under the patent rules.

In particular, it cannot be disputed that Heitz does not expressly disclose Applicants' claimed compounds of 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, or Tribromoerythrosin. To overcome this clear shortcoming, the Examiner cites Heitz as disclosing a formulation comprising derivatives of fluorescein and these derivatives may have one or more substituents in the 4, 5, 6, 7, 2', 4', 5' and 7' positions selected from the group consisting of fluoro, chloro, bromo, iodo, and etc. The Examiner then contends that this formulation encompasses Applicants' recited compounds, such as 4,5,6,7-Tetrabromoerythrosin.



As Applicants previously explained, such a contention is not a proper anticipation of the claims. More specifically, MPEP §2132.02 states that:

**"A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE "AT ONCE ENVISAGED" FROM THE FORMULA**

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962)."

In the present case, Heitz discloses at col. 4, lines 21-26, which is relied upon by the Examiner in the Office Action, "[t]he derivatives of fluorescein (C.I. No. 45350) having one or more substituents in the 4, 5, 6, 7, 2', 4', 5' and 7' positions selected from the group consisting of F, Cl, Br, I, --NO<sub>2</sub>, --COOH and --OH are especially important." Hence, Heitz is discussing the possibility of substitution at one or more of 8 positions with one of 7 different elements or functionalities. This clearly is not the limited class discussed in MPEP 2131.02. In fact, it is believed that there are over 5 million possible combinations in this disclosure in Heitz. See Hersey Declaration ¶9. This is not a situation where one skilled in the art could at once envisage the claimed compounds of the present application. Only through the use of hindsight reconstruction using the claimed compounds as a blueprint or endless experimentation could one skilled in the art arrive at the claimed compound

from this disclosure in Heitz. Therefore, in accordance with MPEP 2131.02, Heitz cannot be said to anticipate the claimed compound.

The Examiner appears to now agree with Applicants and has changed the rejection to one of obviousness under 35 USC §103(a). However, MPEP 2144.08 provides a guide for the Examiner in making such a rejection which includes following the factors set out by the U.S. Supreme Court in Graham v. John Deere. Such an analysis does not appear to have been conducted in this rejection. As noted in MPEP 2144.08, the mere fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient to establish a prima facie case of obviousness. See In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed Cir. 1994). Baird is especially on point with regard to this case (Applicants are including a copy of this case herewith for the Examiner's review). In Baird, the Federal Circuit found that "[w]hile the Knapp formula [prior art] unquestionably encompasses bisphenol A [of claimed compound] when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables." 29 USPQ2d at 1552. The Court then held that "[a] disclosure of millions of compounds does not render obvious a claim to three compounds..." and reversed the obviousness rejection.

In this case, as explained above and in Dr. Hersey's declaration, there are over 5 million possible combinations in the disclosure in Heitz relied upon by Examiner. See Hersey Declaration ¶9. The claimed compounds are merely 4 of those over 5 million. In accordance with Baird, the disclosure of millions of compounds in Heitz does not render the claimed 4 compounds obvious. Further, as stated in MPEP 2144.08, the Federal Circuit requires that there be some reasonable likelihood of success for the proposed modification. Being 4 of over 5 million does not provide any reasonable likelihood of success.

This is clearly not an example of routine experimentation since, other than by blind luck, it would take one skilled in the art many lifetimes to use the disclosure in Heitz and arrive at any of the claimed compounds. See Hersey Declaration ¶9.

In addition, one of ordinary skill in the art would not have made the Examiner's hypothetical manipulation and modifications of the known halogenated xanthene dyes to arrive at the claimed invention, and there is no motivation for one of ordinary skill in the art to make such modifications. More specifically, Heitz is concerned with certain optical properties of *known* halogenated xanthenes, and thus provides no motivation for conceptualization or investigation of the highly-halogenated molecules of independent Claims 1, 36 and 37. See Hersey Declaration ¶10.

Furthermore, Heitz does not disclose or suggest the presently claimed therapeutic compositions or chemotherapeutic treatments. Instead of teachings directed to pharmaceutical compositions for treatment of diseases of human tissue (as is the subject of Applicants' claimed invention), Heitz is directed to *pesticidal compositions and their uses in livestock* (i.e., *ex vivo* killing of intestinal parasites to prevent infection, wherein the pathogenic organisms are killed by exposure to light outside of the infected animal before they can infect another animal). Heitz is not directed to nor does it disclose or suggest an injectable chemotherapeutic composition for human use (as required in Claims 1, 36 and 37 of the present application). In fact, the subject matter of Heitz is so far removed from the subject matter of the claimed invention, that one skilled in the art would not be motivated in any way to rely or refer to this reference for compositions for treatment of diseases of human tissue, as in the claimed invention. See Hersey Declaration ¶11.

For at least the above-stated reasons, Heitz fails to disclose or suggest the pharmaceutical compositions and medicaments of the present application, and the Examiner has failed to make out

a prima facie case of obviousness. Even if a prima facie case has been established, Applicants have clearly rebutted it in this response, especially in light of the Declaration of Dr. Hersey evidencing the non-obviousness of the claimed compounds and invention. Accordingly, the claims of the present application are clearly patentable over the cited reference, and it is respectfully requested that this rejection be withdrawn.

#### Interview Request

If the Examiner still wishes to reject the claims of the present application after considering this amendment, then Applicants request an interview with the Examiner to discuss the rejections in further depth. In such a case, it is respectfully requested that the Examiner contact the undersigned to set-up such an interview prior to the issuance of a further Office Action for this application.

#### Conclusion

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an allowable condition and should be allowed.

If any fee should be due for this amendment, RCE or declaration, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

Date: July 5, 2007

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Plaintiff points to its own actions as evidence of its apprehension of suit. For example, it cites a letter that its patent counsel sent to Defendant regarding its position that it was not infringing the '559 patent. (Pl. Br. at 8; Pl. Exh. C.)

The court is not persuaded that Plaintiff's own perceptions of Defendant's actions constitute the type of objective evidence required to prove a reasonable apprehension of suit. Rather, the "apprehension of suit" prong of the relevant test, described above, focuses on the defendant's, not plaintiff's conduct. *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 [6 USPQ2d 1685] (Fed. Cir. 1988).

In conclusion, the court is not persuaded that Plaintiff has a reasonable apprehension of suit by Defendant. Defendant has not sued Plaintiff, nor threatened to sue Plaintiff, nor made any demands on Plaintiff; moreover, there has been no evidence submitted that Defendant is threatening to sue other parties who produce the same items as Plaintiff. Thus, Plaintiff has failed to indicate that there is before this court a justiciable case or controversy, permitting analysis of the propriety of declaratory judgment. Because Plaintiff has failed to indicate that it has a reasonable apprehension of suit by Defendant, the court need not address the second prong of the applicable analysis — whether or not it has actually produced or prepared to produce the allegedly infringing product. Defendant's motion will be granted. An appropriate order will be issued.

#### ORDER

In accordance with the accompanying memorandum, IT IS HEREBY ORDERED THAT:

(1) Defendant's motion to dismiss is GRANTED.

(2) The clerk of court is directed to close this case.

#### Court of Appeals, Federal Circuit

In re Baird

No. 93-1262

Decided January 19, 1994

#### PATENTS

##### 1. Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (§115.0903.03)

Application claim for flash fusible toner is not obvious in view of prior patent, even

though generic diphenol formula of patent encompasses bisphenol A of claim, since disclosure of generic formula that may encompass claimed compound does not, without more, render compound obvious, and since generic diphenol formula of patent contains large number of variables and encompasses estimated 100 million different diphenols in addition to bisphenol, but patent does not suggest selection of specific variables to formulate that compound and specifically discloses diphenols which are different from, and more complex than, bisphenol A; prior patent's specific enumeration of derivatives of bisphenol A does not warrant contrary conclusion, since suggestion of certain complex bisphenol A derivatives does not describe or suggest bisphenol A itself and thus does not motivate its selection.

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Brian W. Baird, Art F. Diaz, William H. Dickstein and Charles M. Seymour, serial no. 07/333,524 (flash fusible toner resins). From decision upholding examiner's final rejection of claims 1-5 on ground of obviousness under 35 USC 103, applicants appeal. Reversed.

John A. Brady, Lexington, Ky., for appellant.

Adrienne B. Lepiane, assistant solicitor, PTO (Fred E. McKelvey, solicitor, and Richard E. Schafer, associate solicitor, with her on brief), for appellee.

Before Michel, Plager, and Lourie, circuit judges.

Lourie, J.

Applicants Brian W. Baird, Art F. Diaz, William H. Dickstein, and Charles M. Seymour (collectively Baird)<sup>1</sup> appeal from the October 15, 1992 decision of the U.S. Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences, Appeal No. 92-0860, affirming the examiner's final rejection of claims 1-5 of application Serial No. 07/333,524, entitled "Flash Fusible Toner Resins," as unpatentable on the ground of obviousness under 35 U.S.C. § 103 (1988). We reverse.

<sup>1</sup> The real party in interest is Lexmark International, Inc.

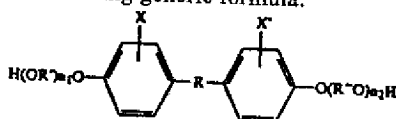
## BACKGROUND

Baird's application is directed to a flash fusible toner comprising a polyester of bisphenol A and an aliphatic dicarboxylic acid. Synthesis of the toner compositions involves the acetylation of bisphenol A and the reaction of that product with an aliphatic dicarboxylic acid selected from the group consisting of succinic acid, glutaric acid, and adipic acid.<sup>2</sup> The application discloses that toners containing bisphenol A have optimal characteristics for flash fusing including, *inter alia*, high thermal stability and low critical surface energy.

Claim 1, the only claim at issue, reads as follows:

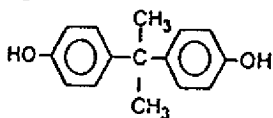
1. A flash fusible toner comprising a binder resin which is a bisphenol A polyester containing an aliphatic di[carboxylic] acid selected from the group consisting of succinic acid, glutaric acid and adipic acid.

Claim 1 stands rejected as obvious over U.S. Patent 4,634,649 to Knapp et al., which relates to developer compositions comprised of, *inter alia*, the polymeric esterification product of a dicarboxylic acid and a diphenol of the following generic formula:

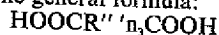


wherein R is selected from substituted and unsubstituted alkylene radicals having from about 2 to about 12 carbon atoms, alkylidene radicals having from 1 to 12 carbon atoms and cycloalkylidene radicals having from 3 to 12 carbon atoms; R' and R'' are selected from substituted and unsubstituted alkylene radicals having from 2 to 12 carbon atoms, alkylene arylene radicals having from 8 to 12 carbon atoms and arylene radicals; X and X' are selected from hydrogen or an alkyl radical having from 1 to 4 carbon atoms; and each n is a number from 0 (zero) to 4.

Col. 4, lines 16-38. The Knapp formula contains a broad range of variables and thus encompasses a large number of different diphenols, one of which is bisphenol A, which is shown in Baird's application as having the following structure:



Knapp also discloses that the dicarboxylic acids have the general formula:



wherein R'' is a substituted or unsubstituted alkylene radical having from 1 to 12 carbon atoms, arylene radicals or alkylene arylene radicals having from 10 to 12 carbon atoms and n<sub>1</sub> is a number of less than 2.

Col. 5, lines 6-14. Twenty typical dicarboxylic acids are recited, including succinic acid, glutaric acid, and adipic acid, the dicarboxylic acids recited in claim 1.

The examiner rejected claim 1 as obvious on the ground that Knapp specifically discloses as components of his esters the three dicarboxylic acids recited in claim 1 and a generic formula which encompasses bisphenol A. Recognizing that bisphenol A is defined when certain specific variables are chosen, the examiner reasoned that bisphenol A "may be easily derived from the generic formula of the diphenol in [Knapp] and all the motivation the worker of ordinary skill in the art needs to arrive at the particular polyester of the instant claim[ ] is to follow [that formula]."

The Board upheld the examiner's rejection. It rejected Baird's argument that there was no motivation for one to select bisphenol A from Knapp and summarily concluded that "the fact that [the claimed] binder resin is clearly encompassed by the generic disclosure of Knapp . . . provides ample motivation for the selection of [the claimed composition]." Slip op. at 3. The Board's decision was affirmed on reconsideration.

## DISCUSSION

The only issue before us is whether the record supports the Board's conclusion that, in view of the teachings of Knapp, the claimed compounds<sup>2</sup> would have been obvious to one of ordinary skill in the art. We review an obviousness determination by the Board *de novo*, while we review underlying factual findings for clear error. *In re Beattie*, 974 F.2d 1309, 1311, 24 USPQ2d 1040, 1041 (Fed. Cir. 1992).

Baird does not dispute the fact that the generic diphenol formula of Knapp encompasses bisphenol A. Nor does Baird dispute that Knapp specifically discloses the three dicarboxylic acids recited in claim 1. Rather, Baird argues that there is no suggestion in Knapp to select bisphenol A from the vast

<sup>2</sup>Since the toner, the resin, and the polyester compounds appear to be treated in the Board opinion and patent application as synonymous, and the PTO has premised its obviousness rejection on the obviousness of the compounds, we will treat this case accordingly.

number of diphenols covered by the generic formula and that the Board thus erred in concluding that the claimed compounds would have been obvious.

[1] What a reference teaches is a question of fact. *Beattie*, 974 F.2d at 1311, 24 USPQ2d at 1041. The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (rejecting Commissioner's argument that "regardless [ ] how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it"). *Jones* involved an obviousness rejection of a claim to a specific compound, the 2-(2'-aminoethoxy)ethanol salt of 2-methoxy-3,6-dichlorobenzoic acid (dicamba), as obvious in view of, *inter alia*, a prior art reference disclosing a genus which admittedly encompassed the claimed salt. We reversed the Board's rejection, reasoning that the prior art reference encompassed a "potentially infinite genus" of salts of dicamba and listed several such salts, but that it did not disclose or suggest the claimed salt. *Id.*

In the instant case, the generic diphenol formula disclosed in Knapp contains a large number of variables, and we estimate that it encompasses more than 100 million different diphenols, only one of which is bisphenol A. While the Knapp formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables. Indeed, Knapp appears to teach away from the selection of bisphenol A by focusing on more complex diphenols, including 2,2-bis(4-beta-hydroxyethoxyphenyl) propane, 2,2-bis(4-hydroxypropoxyphenyl) propane, and 2,2-bis(4-hydroxyisopropoxyphenyl)propane. Col. 4, lines 51-64. Knapp teaches that in preferred diphenols, R has 2 to 4 carbon atoms and R' and R'' have 3 to 4 carbon atoms, and in "optimum" diphenols, R is an isopropylidene radical, R' and R'' are selected from the group consisting of propylene and butylene radicals, and n is one. Col. 4, lines 38-47. Knapp further states that the diphenol in the preferred polyester material is 2,2-bis(4-hydroxyisopropoxyphenyl)propane. Col. 5, lines 36-38. Fifteen typical diphenols are recited. None of them, or any of the other preferred phenols recited above, is or suggests bisphenol A.

The Commissioner repeatedly emphasizes that many of the diphenols specifically enumerated in Knapp are derivatives of bisphenol A. He argues that Knapp thus sug-

gests the selection of bisphenol A itself. We disagree, because, according to the specification, the diphenol in the esters of claim 1 can only be bisphenol A, not a bisphenol A derivative. While Knapp may suggest certain complex bisphenol A derivatives, it does not describe or suggest bisphenol A and therefore does not motivate the selection of bisphenol A.

"[A] reference must be considered not only for what it expressly teaches, but also for what it fairly suggests." *In re Burckel*, 592 F.2d 1175, 1179, 201 USPQ 67, 70 (CCPA 1979). Given the vast number of diphenols encompassed by the generic diphenol formula in Knapp, and the fact that the diphenols that Knapp specifically discloses to be "typical," "preferred," and "optimum" are different from and more complex than bisphenol A, we conclude that Knapp does not teach or fairly suggest the selection of bisphenol A. *See In re Belle* 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993) (DNA sequence would not have been obvious in view of prior art reference suggesting a nearly infinite number of possibilities and failing to suggest why among all those possibilities one would seek the claimed sequence). A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.

#### CONCLUSION

The Board clearly erred in finding that Knapp would have provided the requisite motivation for the selection of bisphenol A in the preparation of the claimed compounds. Accordingly, the decision of the Board affirming the rejection of claim 1 as obvious over Knapp is reversed.

#### COSTS

No costs.

#### REVERSED

#### Court of Appeals, Fifth Circuit

McGaughey v. Twentieth Century Fox Television

No. 93-1652

Decided January 20, 1994

#### COPYRIGHTS

1. Rights in copyright; infringement — Right to reproduction — Access, copying, and substantial similarity — In general (§213.0503.01)

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